Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were completed in July 2014.

Original Approvals

This section displays the original approval. To read the complete approval, please refer to 21 CFR Parts 500 and the related Federal Register notices.

NADA Number: 141-421

Trade Name:	Duocare™
Ingredients:	Ivermectin/praziquantel
Sponsor:	Merial Ltd.
Approval Date:	May 12, 2014
Status:	OTC
Route:	Oral
Species:	Horses
Drug Form:	Paste
Concentration:	Ivermectin 1.87%/praziquantel 23.38%
Indications:	For the treatment and control of the following parasites in horses over 5 months of age: **Tapeworms** *Anoplocephala perfoliata*; **Large Strongyles** (adults) - *Strongylus vulgaris* (also early forms in blood vessels), *S. edentatus* (also tissue stages), *S. equinus*, *Triodontophorus* spp. including *T. brevicauda* and *T. serratus*, and *Craterostomum acuticaudatum*; **Small Strongyles** (adults, including those resistant to some benzimidazole class compounds) - *Coronocyclus* spp. including *C. coronatus*, *C. labiatus* and *C. labratus*; *Cyathostomum* spp. including *C. catinatum* and *C. pateratum*; *Cylicocyclus* spp. including *C. insigne*, *C. leptostomum*, *C. nassatus* and *C. brevicapsulatus*; *Cylicodontophorus* spp. *Cylicostephanus* spp. including *C. calicatus*, *C. goldi*, *C. longibursatus* and *C. minutus*, and *Petrovinema poculatum*; **Small Strongyles** - Fourth-stage larvae; **Pinworms** (adults and fourth-stage larvae)- *Oxyuris equi*; **Ascarids** (adults and third- and fourth-stage larvae) - *Parascaris equorum*; **Hairworms** (adults) - *Trichostrongylus axei*; **Large-mouth Stomach Worms** (adults) - *Habronema muscae*; **Bots** (oral and gastric stages) - *Gasterophilus* spp. including *G. intestinalis* and *G. nasalis*; **Lungworms** (adults and fourth-stage larvae) - *Dictyocaulus arnfieldi*; **Intestinal Threadworms** (adults) - *Strongyloides westeri*; **Summer Sores** caused by *Habronema* and *Draschia* spp. cutaneous third-stage larvae; Dermatitis caused by neck threadworm microfilariae, *Onchocerca* sp.
Exclusivity:	3 years

NADA Number: 141-426

Trade Name:	Bravecto™
Ingredients:	Fluralaner
Sponsor:	Intervet, Inc.
Approval Date:	May 15, 2014
Status:	RX
Route:	Oral
Species:	Dogs
Drug Form:	Chewable Tablet
Concentration:	Each chewable tablet contains 112.5, 250, 500, 1000, or 1400 mg fluralaner.
Indications:	Bravecto™ kills adult fleas and is indicated for the treatment and prevention of flea infestations (*Ctenocephalides felis*), and the treatment and control of tick infestations [*Ixodes scapularis* (black-legged tick), *Dermacentor variabilis* (American dog tick), and *Rhipicephalus sanguineus* (brown dog tick)] for 12 weeks in dogs and puppies 6 months of age and older, and weighing 4.4 pounds or greater. Bravecto™ is also indicated for the treatment and control of *Amblyomma americanum* (lone star tick) infestations for 8 weeks in dogs and puppies 6 months of age and older, and weighing 4.4 pounds or greater.
Exclusivity:	5 years
Patent:	Patent Number Expiration date:

8,022,089	March 4, 2025
8,492,311	March 4, 2025
7,662,972	April 26, 2025

NADA Number: 141-427

Trade Name:	Osphos®
Ingredients:	Clodronate
Sponsor:	Dechra, Ltd.
Approval Date:	April 28, 2014
Status:	RX
Route:	Intramuscular injection
Species:	Horses
Drug Form:	Injection
Concentration:	60 mg clodronate disodium per mL
Indications:	For the control of clinical signs associated with navicular syndrome in horses.
Exclusivity:	5 years
Patent:	Patent Number Expiration date:
	7,781,420 November 9, 2026

NADA Number: 141-431

Trade Name:	FOLLTROPIN®
Ingredients:	Porcine pituitary-derived follicle stimulating hormone
Sponsor:	Bioniche Animal Health USA, Inc.
Approval Date:	July 13, 2014
Status:	RX
Route:	Intramuscular injection
Species:	Cattle/beef and dairy heifers and cows
Drug Form:	Solution for injection
Concentration:	700 IU FSH/vial (equivalent to 400 mg NIH-FSH-P1); when reconstituted, the final solution contains 35 IU/mL FSH.
Indications:	For the induction of superovulation in beef and dairy heifers and cows.
Exclusivity:	3 years

NADA Number: 141-434

Trade Name:	Simbadol™
Ingredients:	Buprenorphine
Sponsor:	Abbott Laboratories
Approval Date:	July 18, 2014
Status:	RX
Route:	Subcutaneous injection
Species:	Cats
Drug Form:	Injectable
Concentration:	Each milliliter of solution contains 1.8 milligrams buprenorphine.
Indications:	For the control of postoperative pain associated with surgical procedures in cats.
Exclusivity:	5 years

NADA Number: 141-348

Trade Name:	SYNOVEX® ONE FEEDLOT, SYNOVEX® ONE GRASS
Ingredients:	Trenbolone acetate and estradiol benzoate
Sponsor:	Zoetis Inc.
Approval Date:	July 31, 2014
Status:	OTC
Route:	Implantation
Species:	SYNOVEX® ONE FEEDLOT: Steers and heifers fed in confinement for slaughter SYNOVEX® ONE GRASS: Pasture steers and heifers (slaughter, stocker and feeder)
Drug Form:	Extended release implant
Concentration:	Each pellet contains 25 mg trenbolone acetate and 3.5 mg estradiol benzoate in an extended release coating.

	One SYNOVEX® ONE FEEDLOT implant (eight pellets) contains 200 mg trenbolone acetate and 28 mg estradiol benzoate. One SYNOVEX® ONE GRASS implant (six pellets) contains 150 mg trenbolone acetate and 21 mg estradiol benzoate.
Indications:	SYNOVEX® ONE FEEDLOT: For increased rate of weight gain and improved feed efficiency for up to 200 days in steers and heifers fed in confinement for slaughter. SYNOVEX® ONE GRASS: For increased rate of weight gain for up to 200 days in pasture steers and heifers (slaughter, stocker and feeder).
Exclusivity:	3 years
Patent:	Patent Number Expiration date: 6,022,554 December 15, 2017

NADA Number: 141-423

Trade Name:	HALAMID® AQUA
Ingredients:	Chloramine-T trihydrate
Sponsor:	Axcentive SARL
Approval Date:	April 30, 2014
Status:	OTC
Route:	Immersion
Species:	Freshwater-reared salmonids, walleye, freshwater-reared warmwater finfish
Drug Form:	Powder
Concentration:	98.0-100.0% Chloramine-T
Indications:	For the control of mortality in freshwater-reared salmonids due to bacterial gill disease associated with *Flavobacterium* spp. For the control of mortality in walleye due to external columnaris disease associated with *Flavobacterium columnare.* For the control of mortality in freshwater-reared warmwater finfish due to external columnaris disease associated with *Flavobacterium columnare.*
Exclusivity:	7 years

ANADA Number: 200-513

Trade Name:	Enroflox™ Injection for Dogs 2.27%
Pioneer:	Baytril® Antibacterial Injectable Solution
Ingredients:	Enrofloxacin
Sponsor:	Norbrook Laboratories, Ltd.
Approval Date:	May 8, 2014
Status:	Rx
Route:	Intramuscular
Species:	Dogs
Drug Form:	Injectable Solution
Concentration:	22.7 mg/mL
Indications:	For the management of diseases in dogs associated with bacteria susceptible to enrofloxacin.

ANADA Number: 200-520

Trade Name:	Carprieve® Injection
Pioneer:	Rimadyl® Injectable
Ingredients:	Carprofen
Sponsor:	Norbrook Laboratories, Ltd.
Approval Date:	July 12, 2014
Status:	Rx
Route:	Subcutaneous injection
Species:	Dogs
Drug Form:	Injectable Solution
Concentration:	Each milliliter (mL) contains 50 milligrams (mg) of carprofen.
Indications:	For the relief of pain and inflammation associated with osteoarthritis and for the control of postoperative pain associated with soft tissue and orthopedic surgeries in dogs.

ANADA Number: 200-530

Trade Name: Paylean® plus Tylovet®
Pioneer: Paylean® plus Tylan®
Ingredients: Ractopamine hydrochloride and tylosin phosphate
Sponsor: Huvepharma AD
Approval Date: May 21, 2014
Status: OTC
Route: Oral, in feed
Species: Finishing swine
Drug Form: Type A medicated article
Concentration: Ractopamine hydrochloride – 9 to 45.4 g/lb
Tylosin phosphate – 100 g/lb
Indications: Ractopamine hydrochloride 4.5 to 9.0 g/ton and tylosin phosphate 40 to 100 g/ton for 2 to 6 weeks immediately after medicating with 250 mg tylosin tartrate (as Tylan® Soluble) per gallon in drinking water for 3 to 10 days: For increased rate of weight gain, improved feed efficiency and increased carcass leanness in finishing swine, weighing not less than 150 lbs, fed a complete ration containing at least 16% crude protein for the last 45 to 90 lbs of gain prior to slaughter; for treatment and control of swine dysentery associated with *Brachyspira hyodysenteriae*; and for control of porcine proliferative enteropathies (PPE, ileitis) associated with *Lawsonia intracellularis*.
Ractopamine hydrochloride 4.5 to 9.0 g/ton and tylosin phosphate 100 g/ton for at least 3 weeks followed by 40 g/ton until market weight: For increased rate of weight gain, improved feed efficiency and increased carcass leanness in finishing swine, weighing not less than 150 lbs, fed a complete ration containing at least 16% crude protein for the last 45 to 90 lbs of gain prior to slaughter; for control of swine dysentery associated with *Brachyspira hyodysenteriae*; and for control of porcine proliferative enteropathies (PPE, ileitis) associated with *Lawsonia intracellularis*.
Ractopamine hydrochloride 4.5 to 9.0 g/ton and tylosin phosphate 100 g/ton: For increased rate of weight gain, improved feed efficiency and increased carcass leanness in finishing swine, weighing not less than 150 lbs, fed a complete ration containing at least 16% crude protein for the last 45 to 90 lbs of gain prior to slaughter; and for control of porcine proliferative enteropathies (PPE, ileitis) associated with *Lawsonia intracellularis*.

ANADA Number: 200-558

Trade Name: Engain™ plus Tylan®
Pioneer: Paylean® plus Tylan®
Ingredients: Ractopamine hydrochloride plus tylosin phosphate
Sponsor: Zoetis Inc.
Approval Date: May 29, 2014
Status: OTC
Route: Oral, in feed
Species: Finishing swine
Drug Form: Type A medicated article
Concentration: Ractopamine hydrochloride – 9 or 45.4 g/lb
Tylosin phosphate – 40 and 100 g/lb
Indications: Ractopamine hydrochloride (4.5 to 9.0 g/ton) in combination with tylosin phosphate (40 or 100 g/ton): For increased rate of weight gain, improved feed efficiency and increased carcass leanness in finishing swine, weighing not less than 150 lbs, fed a complete ration containing at least 16% crude protein for the last 45 to 90 lbs of gain prior to slaughter; for control of swine dysentery associated with *Brachyspira hyodysenteriae*; and for control of porcine proliferative enteropathies (PPE, ileitis) associated with *Lawsonia intracellularis*.
Ractopamine hydrochloride (4.5 to 9.0 g/ton) in combination with tylosin phosphate (100 g/ton): For increased rate of weight gain, improved feed efficiency and increased carcass leanness in finishing swine, weighing not less than 150 lbs, fed a complete ration containing at least 16% crude protein for the last 45 to 90 lbs of gain prior to slaughter; and for control of porcine proliferative enteropathies (PPE, ileitis) associated with *Lawsonia intracellularis*.
Ractopamine hydrochloride (4.5 to 9.0 g/ton) in combination with tylosin phosphate (40 to 100 g/ton): For increased rate of weight gain, improved feed efficiency and increased carcass leanness in finishing swine, weighing not less than 150 lbs, fed a complete ration containing at least 16% crude protein for the last 45 to 90 lbs of gain prior to slaughter; for treatment and control of

swine dysentery associated with *Brachyspira hyodysenteriae*; and for control of porcine proliferative enteropathies (PPE, ileitis) associated with *Lawsonia intracellularis*.

ANADA Number: 200-559

Trade Name:	Actogain™ 45 plus Rumensin®
Pioneer:	Optaflexx™ plus Rumensin®
Ingredients:	Ractopamine hydrochloride plus monensin USP
Sponsor:	Zoetis Inc.
Approval Date:	July 18, 2014
Status:	OTC
Route:	Oral, in feed
Species:	Cattle fed in confinement for slaughter
Drug Form:	Type A medicated article
Concentration:	Ractopamine hydrochloride – 45.4 g/lb Monensin USP – 90.7 g/lb
Indications:	Ractopamine hydrochloride (8.2 to 24.6 g/ton) in combination with monensin USP (10 to 40 g/ton): For increased rate of weight gain, improved feed efficiency and prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii* in cattle fed in confinement for slaughter during the last 28 to 42 days on feed. Ractopamine hydrochloride (9.8 to 24.6 g/ton) in combination with monensin, USP (10 to 40 g/ton): For increased rate of weight gain, improved feed efficiency, increased carcass leanness and prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii* in cattle fed in confinement for slaughter during the last 28 to 42 days on feed. Ractopamine (not to exceed 800 g/ton) in combination with a complete feed containing monensin USP (10 to 40 g/ton): For increased rate of weight gain and improved feed efficiency, prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii* in cattle fed in confinement for slaughter during the last 28 to 42 days on feed.

ANADA Number: 200-560

Trade Name:	Actogain™ 45 plus Rumensin® plus MGA®
Pioneer:	Optaflexx™ plus Rumensin® plus MGA®
Ingredients:	Ractopamine hydrochloride plus monensin USP plus melengestrol acetate
Sponsor:	Zoetis Inc.
Approval Date:	June 2, 2014
Status:	OTC
Route:	Oral, in feed
Species:	Heifers fed in confinement for slaughter
Drug Form:	Type A medicated article
Concentration:	Ractopamine hydrochloride – 45.4 g/lb Monensin USP – 90.7 g/lb Melengestrol acetate – 200 and 500 g/lb
Indications:	For increased rate of weight gain, improved feed efficiency, increased carcass leanness, prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*, and suppression of estrus (heat) in heifers fed in confinement for slaughter for the last 28 to 42 days on feed.

ANADA Number: 200-561

Trade Name:	Actogain™ 45 plus Rumensin® plus Tylan®
Pioneer:	Optaflexx™ plus Rumensin® plus Tylan®
Ingredients:	Ractopamine hydrochloride, monensin USP, and tylosin phosphate
Sponsor:	Zoetis Inc.
Approval Date:	May 30, 2014
Status:	OTC
Route:	Oral, in feed
Species:	Cattle fed in confinement for slaughter
Drug Form:	Type A medicated article
Concentration:	Ractopamine hydrochloride – 45.4 g/lb Monensin USP – 90.7 g/lb

Tylosin phosphate – 40 and 100 g/lb

Indications: Ractopamine hydrochloride (8.2 to 24.6 g/ton) in combination with monensin sodium (10 to 40 g/ton) and tylosin phosphate (8 to 10 g/ton): For increased rate of weight gain, improved feed efficiency, prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii* and reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium (Actinomyces) pyogenes* in cattle fed in confinement for slaughter for the last 28 to 42 days on feed.
Ractopamine hydrochloride (9.8 to 24.6 g/ton) in combination with monensin sodium (10 to 40 g/ton) and tylosin phosphate (8 to 10 g/ton): For increased rate of weight gain, improved feed efficiency, increased carcass leanness, prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii* and reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium (Actinomyces) pyogenes* in cattle fed in confinement for slaughter for the last 28 to 42 days on feed.
Ractopamine hydrochloride top dress (not to exceed 800g/ton) plus monensin sodium (10 to 40 g/ton) in combination with tylosin phosphate (8 to 10 g/ton): For increased rate of weight gain, improved feed efficiency, prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii* and reduction in incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium (Actinomyces)* pyogenes in cattle fed in confinement for slaughter during the last 28 to 42 days on feed.

ANADA Number: 200-562

Trade Name: Actogain™ 45 plus Rumensin® plus Tylan® plus MGA®
Pioneer: Optaflexx™ plus Rumensin® plus Tylan® plus MGA®
Ingredients: Ractopamine hydrochloride, monensin USP, tylosin phosphate, and melengestrol acetate
Sponsor: Zoetis Inc.
Approval Date: June 2, 2014
Status: OTC
Route: Oral, in feed
Species: Heifers fed in confinement for slaughter
Drug Form: Type A medicated article
Concentration: Ractopamine hydrochloride – 45.4 g/lb
Monensin USP – 90.7 g/lb
Tylosin phosphate – 40 and 100 g/lb
Melengestrol acetate – 200 and 500 mg/lb
Indications: For increased rate of weight gain, improved feed efficiency, increased carcass leanness, prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*, reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium (Actinomyces) pyogenes* and suppression of estrus (heat) in heifers fed in confinement for slaughter for the last 28 to 42 days on feed.

ANADA Number: 200-566

Trade Name: Optaflexx™ 45 plus Rumensin® plus Tylovet® 100
Pioneer: Optaflexx™ plus Rumensin® plus Tylan®
Ingredients: Ractopamine hydrochloride, monensin USP, and tylosin phosphate
Sponsor: Huvepharma AD
Approval Date: July 27, 2014
Status: OTC
Route: Oral, in feed
Species: Cattle fed in confinement for slaughter
Drug Form: Type A medicated article
Concentration: Ractopamine hydrochloride – 45.4 g/lb
Monensin USP – 90.7 g/lb
Tylosin phosphate –100 g/lb
Indications: Ractopamine hydrochloride (8.2 to 24.6 g/ton) in combination with monensin USP (10 to 40 g/ton) and tylosin phosphate (8 to 10 g/ton): For increased rate of weight gain, improved feed efficiency, prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii* and reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium (Actinomyces)*

pyogenes in cattle fed in confinement for slaughter for the last 28 to 42 days on feed.
Ractopamine hydrochloride (9.8 to 24.6 g/ton) in combination with monensin USP (10 to 40 g/ton) and tylosin phosphate (8 to 10 g/ton): For increased rate of weight gain, improved feed efficiency, increased carcass leanness, prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii* and reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium (Actinomyces) pyogenes* in cattle fed in confinement for slaughter for the last 28 to 42 days on feed.
Ractopamine hydrochloride top dress (not to exceed 800 g/ton) plus monensin USP (10 to 40 g/ton) in combination with tylosin phosphate (8 to 10 g/ton): For increased rate of weight gain, improved feed efficiency, prevention and control of coccidiosis due to Eimeria bovis and E. zuernii and reduction of incidence of liver abscesses caused by Fusobacterium necrophorum and Arcanobacterium (Actinomyces) pyogenes in cattle fed in confinement for slaughter during the last 28 to 42 days on feed.

ANADA Number: 200-567

Trade Name:	Optaflexx™ 45 plus Rumensin® plus Tylovet® 100 plus MGA®
Pioneer:	Optaflexx™ plus Rumensin® plus Tylan® plus MGA®
Ingredients:	Ractopamine hydrochloride, monensin USP, tylosin phosphate, and melengestrol acetate
Sponsor:	Huvepharma AD
Approval Date:	July 18, 2014
Status:	OTC
Route:	Oral, in feed
Species:	Heifers fed in confinement for slaughter
Drug Form:	Type A medicated article
Concentration:	Ractopamine hydrochloride – 45.4 g/lb Monensin USP – 90.7 g/lb Tylosin phosphate –100 g/lb Melengestrol acetate – 200 and 500 mg/lb
Indications:	For increased rate of weight gain, improved feed efficiency, increased carcass leanness, prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*, reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium (Actinomyces) pyogenes*, and suppression of estrus (heat) in cattle (heifers) fed in confinement for slaughter for the last 28 to 42 days on feed.

ANADA Number: 200-569

Trade Name:	Tylan® plus Sacox®
Pioneer:	Tylan® plus Bio-Cox®
Ingredients:	Tylosin phosphate and salinomycin sodium
Sponsor:	Huvepharma AD
Approval Date:	July 12, 2014
Status:	OTC
Route:	Oral, in feed
Species:	Broiler chickens
Drug Form:	Type A medicated article
Concentration:	Tylosin phosphate – 10, 40, or 100 g/lb Salinomycin sodium – 30 or 60 g/lb
Indications:	For increased rate of weight gain and improved feed efficiency, and as an aid in the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati* in broiler chickens.

ANADA Number: 200-570

Trade Name:	Tylovet®100 plus Bio-cox®
Pioneer:	Tylan® plus Bio-Cox®
Ingredients:	Tylosin phosphate and salinomycin sodium
Sponsor:	Huvepharma AD
Approval Date:	July 12, 2014
Status:	OTC

Route:	Oral, in feed
Species:	Broiler chickens
Drug Form:	Type A medicated article
Concentration:	Tylosin phosphate –100 g/lb Salinomycin sodium – 30 or 60 g/lb
Indications:	For increased rate of weight gain and improved feed efficiency, and as an aid in the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati* in broiler chickens.

Supplemental Approvals

This section displays the change(s) to the original approval. To read the complete approval, please refer to 21 CFR Parts 500 and the related Federal Register notices.

NADA Number: 013-076

Trade Name:	Tylan® Soluble
Ingredients:	Tylosin Tartrate
Sponsor:	Elanco Animal Health, A Division of Eli Lilly & Co.
Approval Date:	April 17, 2014

This supplement provides for a change in the marketing status from OTC to Rx to conform to GFIs 209 and 213 and to clarify the wording of the approved indication for turkeys.

NADA Number: 035-688

Trade Name:	Aureomix® S Granular
Ingredients:	Sulfamethazine and Chlortetracycline
Sponsor:	Zoetis Inc.
Approval Date:	April 28, 2014

This supplement provides for the approval of a new tradename and reformulation to reflect the withdrawal of approval of procaine penicillin for the production indications of growth promotion and feed efficiency in swine.

NADA Number: 108-901

Trade Name:	Lutalyse® Injection
Ingredients:	Dinoprost tromethamine
Sponsor:	Zoetis Inc.
Approval Date:	June 9, 2014

This supplement provides for a new indication for use with FACTREL (gonadorelin injection) Injection to synchronize estrous cycles to allow fixed-time artificial insemination (FTAI) in lactating dairy cows, and for use with EAZI-BREED CIDR (progesterone intravaginal insert) Cattle Insert for synchronization of estrus in lactating dairy cows; for use with EAZI-BREED CIDR (progesterone intravaginal insert) Cattle Insert for synchronization of estrus in suckled beef cows and replacement beef and dairy heifers, advancement of first postpartum estrus in suckled beef cows, and advancement of first pubertal estrus in beef heifers.

NADA Number: 141-207

Trade Name:	Advocin™ Sterile Injectable Solution
Ingredients:	Danofloxacin
Sponsor:	Zoetis Inc.
Approval Date:	July 16, 2014

This supplement provides for a new indication for the control of BRD in beef cattle at high risk of developing BRD associated with *M. haemolytica* and *P. multocida*.

NADA Number: 141-327

Trade Name:	LONGRANGE™

Ingredients: Eprinomectin
Sponsor: Merial Ltd.
Approval Date: April 16, 2014

This supplement provides for the approval of a new indication for the treatment and control of *Bunostomum phlebotomum* (adults and L4s) and for the protection of cattle from reinfection with *Bunostomum phlebotomum* for 150 days following treatment.

NADA Number: 141-406

Trade Name: NexGard™
Ingredients: Afoxolaner
Sponsor: Merial Ltd.
Approval Date: May 15, 2014

This supplement provides for the treatment and control of Black-legged tick (*Ixodes scapularis*) and Lone Star tick (*Amblyomma americanum*) infestations in dogs and puppies 8 weeks of age and older, weighing 4 pounds of body weight or greater, for one month.

NADA Number: 013-076

Trade Name: Tylan® Soluble
Ingredients: Tylosin Tartrate
Sponsor: Elanco Animal Health, A Division of Eli Lilly & Co.
Approval Date: July 30, 2014

This supplement provides for the addition of the indication for the control of mortality caused by necrotic enteritis (NE) associated with *Clostridium perfringens* in broiler chickens.

NADA Number: 128-686

Trade Name: Bio-Cox®
Ingredients: Salinomycin sodium
Sponsor: Zoetis Inc.
Approval Date: June 17, 2014

This supplement provides for a change to the assay limit to 54.0 – 66.0 g/lb (90.0 – 110.0% of label) from the current 57.0 – 69.0 g/lb (95.0 – 115.0% of label) and to remove the overage of the granular formula.

ANADA Number: 200-473

Trade Name: Tylovet® Soluble
Ingredients: Tylosin Tartrate
Sponsor: Huvepharma AD
Approval Date: June 19, 2014

This supplement provides for a change in marketing status from over-the-counter (OTC) to by veterinary prescription (Rx).

Sponsor Address Change

Dechra, Ltd.

Previous: Dechra House, Jamage Industrial Estate, Talke Pits, Stoke-on-Trent Staffordshire, ST7 1XW United Kingdom

New: Snaygill Industrial Estate, Keighley Rd., Skipton, North Yorkshire, BD23 2RW, United Kingdom

Conditional Approvals

The following conditionally-approved new animal drugs are being removed from the Green Book list since they do not qualify under section 512(n)(4)(A)(i) of the Federal Food, Drug, and Cosmetic Act as new animal drugs which have been approved for safety and effectiveness.

Application Number: 141-308

Trade Name: Kinavet®-CA1
Ingredients: Masitinib mesylate
Sponsor: AB Science

Application Number: 141-422

Trade Name: Paccal Vet®-CA1
Ingredients: Paclitaxel
Sponsor: Oasmia Pharmaceutical AB